

SOMNOscreen[™] plus



UP TO 33 CHANNELS

- AMBULATORY & ONLINE
 - CONTINUOUS SYS/DIA
 BLOOD PRESSURE
 - CONTINUOUS DETERMINATION OF OBSTRUCTION LEVEL
 - WIRELESS REAL-TIME DATA TRANSFER

From a screener to a full PSG System in the palm of your hand

Upgradeable at any time!

- Fully portable Polysomnography System
- Wireless real-time data transmission of all signals to the PC
- Unlimited mobility for the patient and the sleep practitioner
- Wireless online transmission and synchronization of digital video

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SOMNOmedics

SOMNOmedics strives to keep its technology compatible with the latest developments and the latest diagnostic clinical features. We, the SOMNOmedics team, take pride in our technology and have developed an innovative solution for Sleep Diagnostics and Therapy.

It will offer you, the practitioner as well as the patient, a flexible and reliable, easy to use system in the sleep laboratory, patient's home or anywhere else. SOMNOmedics offers the most advanced diagnostic system available.

SOMNOscreen[™] plus

the complete PSG system that allows you to perform <u>all levels of sleep testing in any environment!</u>



Mobility - Sleep studies should be performed wherever it is most suitable for the sleep practitioner and the patient - in the patient's home, a medical office or in a hospital.

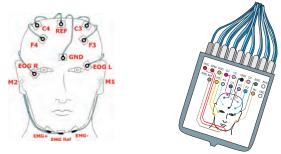
Miniaturization - SOMNOscreen[™] plus, currently the smallest full Polysomnography system available. Featuring up to 33-channels of polysomnoghraphic data, the palm sized unit can store the data on a Compact Flash Card and transmit it to a PC in real-time via a wireless transmitter.

Versatility in application - Basic Respiratory Screening, CPAP/BiPAP/SV Titration, full PSG recording with or without video, 24-hour ambulatory EEG recording, stationary EEGmonitoring with video control or 24 hour ECG and Pulse Oximetry recording. The choice is yours.



Combi-Electrode

Our smallest head box for Home Sleep Test (Level 2) - simplifies sleep quantification during ambulatory tests



PSG Headbox - complies with AASM criteria

Technical Features

- Miniaturized, portable unit, worn by the patient.
- Up to 33 channels 8 channels integrated in base unit.
- Modular design upgradeable at any time.
- Adjustable sampling rates up to 512/s (4096/s optional)
- Continuous display and recording of electrode impedances.
- Display with control keys allows PC independent set-up and operation.
- View and check signals on the display including system status and signal quality.
- Li-lon battery for up to 55 hours of continuous recording and rechargeable without memory effect. The battery can be replaced quickly and easily.
- Data is stored on industry standard High Speed Compact Flash Cards with up to 2 GB capacity or up to 100 hours of PSG recording time.



Wireless real-time data transfer to the PC - A small radio module transfers the data up to 330ft to the PC. Up to 32 systems can be used simultaneously without interference.

Wireless synchronisation of Video and Audio - Video and audio signals are recorded with the compact IR Camera and IR light source and can be transferred wirelessly to the PC up to 330ft away or by LAN.





Sensors

SOMNOmedics has designed and built a new generation of active sensors. They provide excellent signal quality, are less susceptible to interference and reliable for extended periods.

All sensors are silicone embedded and have been proven to be comfortable to wear while remaining mechanically robust and consistent. Quick and easy cleaning allows the sensors to be prepared for the next patient.

Pediatric sensors are also available.

Internal sensors

- Light Sensor: For determining the relevant measurement time (TIB)
- Internal Effort: It is possible to define this sensor as either a thoracic or abdominal effort
- Body Position: Detection of positions: left, right, supine, prone and upright



Pulse Oximeter: A high quality pulse oximeter for recording the SpO₂, pulse rate and pulse waveform. The probe is a comfortable silicone-embedded finger probe

- **Patient Marker:** For the input of relevant time points which the patient may wish to document, for example taking medication, going to the toilet, etc.
- Movement: Detection of movement artefacts

External Sensors



Miniaturized Headbox: 10 referential inputs for EEG/EOG + REF, 2 referential inputs for EMG, 1 differential input for ECG

Combi-Electrode: 2 EEG, 2 EOG



Thermistor: Nasal/Oral Flow



Microphone: Snoring sound



Pressure Sensor: For measuring the CPAP pressure from a CPAP machine, controlling CPAP during titration and measuring flow using a nasal cannula



Effort Sensor: Thoracic and/or abdominal effort (Respiratory Inductive Plethysmography Belts or Strain Gauge Sensor)



Active Sensors: Recording the leg EMG for PLM analysis



Activity Sensor: Estimating the sleep efficiency through activity analysis

ECG Sensor: Recording the ECG with an active three contact sensor for optimized signals

Auxiliary: Input of an external signal

Application

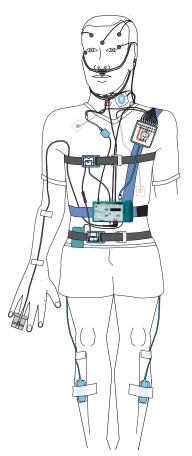
The SOMNOscreenTM plus is positioned directly to either the abdomen or thorax.

Sensor cables are color coded and the connectors are specially keyed, so that only the correct sensor can be plugged into the correct receptacle.

The unit can be programmed to automatically start and run for a pre-programmed duration. All Signals can be checked on the built-in display before recording starts!

Fast transfer of measurement data to the PC after recording. Simply insert the Compact Flash Card in the reader and in less than 20 seconds you are ready to open and analyze the study.

Complete automatic analysis with analysis report printout within 2-3 minutes (see reports below).





SOMNOscreen[™] plus - The only FDA cleared All-In-One **Sleep Diagnostics System**

Software Features

Re-Analyzing: The data can be re-analyzed at any time.

Archiving: The data can be archived to CD, DVD or to a shared network folder (not provided).

Report Generator: Customizable reports and form letters.

Scoring: for Sleep Staging - Manual, semi-manual and automatic scoring; for events - edit by key, by mouse position, by selection window or repeat mode

Patient Data Management (Option): A powerful patient database is available for the efficient organization of all patient data.

- · The sleep profile, graphic results summary and the complete numeric results list are stored.
- The database can produce trend reports comparing different tests done on the same patient. The data is stored in the database even after the case has been archived and deleted from the computer.
- The database is network compatible with a permanent patient list. A search engine is provided to help locate patient data.
- · Calendar with scheduler.

Network link-up: GDT and HL7 Interface for link-up to surgery software or clinic system.

Open Architecture: All results and reports can be exported to MS Excel and SPSS. Raw data can be exported to EDF+ and ASCII format. EDF+ files can be imported into the software. Integration of the data from the database into an existing Practice Management Software.

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Configurations

Signals and Sensors	Cardio- Resp	Home Sleep	PSG	EEG 10-20	EEG 32
Pulse Oxymeter (SpO ₂ , PR, Pulse Waveform)				0	0
Marker Button					
Ambient Light					
Position					
Movement (Magnitude)					
Effort (Thorax)					
Effort (Abdomen)	0	0	0	0	0
2x RIP-Efforts	0	0		0	0
Pneumatic Efforts	0	0	0	0	0
Obstruction Level*	0	0		0	0
Sys/Dia Blood Pressure*	0	0	0	0	0
Flow (Thermistor)	0	0		0	0
Snore (Microphone)	0	0		0	0
PLM left	0			0	0
PLM right	0	0		0	0
PT / Leakage Flow (via ACT)	0	0	0	0	0
Motor Activity	0	0	0	0	0
Flow, CPAP/BiPAP Pressure, Snore (Pressure Sensor, Nasal Cannula)	•	•	•	0	0
10 x EEG / EOG	0	0		0	0
20 x EEG / EOG	0	0	0		0
25 x EEG / EOG	0	0	0	0	
2 x EMG	0	0			
6x EMG	0	0	0	0	
ECG	0				
EEG/EOG-Combi Electrode	0		0	0	0
Wireless Online Data Transfer	0	0	0	0	0
Signal-Check via Cable	0	0	0		
Synchronized, Digital IR Video	0	0	0	0	0
Up to 16 ext. Channels via LAN	0	0	0	0	0
PSG Kit for EEG 10-20				0	
standard O optional *patented					

Options



- Pneumatic based effort sensors
- Data Transfer via DSL / UMTS connection
- EEG/EOG-Combi-Electrode for simplified ambulatory sleep recordings
- Sidestream capnography
- Portable Oesophageal pressure recording with ballon catheter for long term measurements
- Miniaturized Pneumotachograph for CPAP flow recordings and for calibrated breathing volume and leakage determination

- 3-channel ECG

- Multiple Headboxes available
 Dual screen display for viewing data and video separately
 Extended Patient database
 Compact digital IR video camera (optional: wireless transfer module, Pan-Tilt-Zoom function)
- Long term ph-monitor
- Wireless CPAP remote control

Li ION batte Connecto headbox	and marker On button			
Body position Internal effort Flashcard Eject mechanism Pulse oximeter				
8 - 33 CHANNELS MODULAR AND EXPANDABLE				
15 Headbox:	10 EEG/EOG referential + REF, 2 EMG referential, 1 ECG differential, impedance			
10 External:	Abdominal effort, snoring (microphone), nasal/oral flow (thermistor), motor activity, AUX, nasal/oral flow (nasal cannula), PLM L, PLM R, snoring (nasal cannula), CPAP/BiPAP pressure			
8 Internal:	SpO ₂ , pulse rate, pulse waveform, position, move- ment, ambient light, marker button, thoracic effort			
SENSORS				
External Sensors				

DATA PROCESSING

Active Filtering

16 Bit ADC

Sampling Rates adjustable from 4/s to 512/s (optional 4096/s) Small file size through compressed data storage

POWER SUPPLY

Li ION battery (rechargeable), up to 55 hour recording time

SIZE AND WEIGHT

5.51" x 2.83" x 1.1", 9 oz (incl. battery)

SOFTWARE DOMINO

Efficient analysis and scoring software

INTERACTIVE KEYBOARD AND DISPLAY

Signal check on display (blue backlit LCD display) Programmable start and end times Menu controlled display

DATA STORAGE

High-speed Compact Flash Card (up to 2 GB capacity)

OPTIONS

Wireless Online Data Transfer (up to 330ft) - LAN or USB

- Video Synchronized video in DVD quality, 28 frames/sec, using the latest data compression system
 - Audio (20 12.000 Hz)
 - Black and white recording for IR or color recording during daylight
 - Fully synchronized with raw data
 - Playback at different frame speeds (0.1 100 times)
 - Digital zoom function for detailed analysis
 - Easy to edit, cut and archive. Store short sequences on CD or DVD

Analysis

Automatic analysis of all standard signals including:

- Sleep Staging Analysis with Sleep Profile •
- Display of the Sleep Staging Reliability
- Spindle and K-Complex detection
- Micro arousal detection according to the ASDA/AASM • criteria
- Alpha, Beta, Delta and Sigma Frequency Bands from EEG
- REM Detection and REM Density
- PLM detection
- Apnea/Hypopnea calculation according to type and in correlation to Desaturations, Brady/Tachycardia and Micro Arousals
- Oxygen Desaturations
- Snoring •
- Body position
- PTT Pulse Transit Time
- Brady/Tachycardia and Arrhythmia analysis

New information being developed, including:

- Sleep fragmentation based on micro arousal and PTT arousal analysis
- Flow Limitation Obstruction Level Analysis*
- Blood pressure Display of the systolic and diastolic Blood Pressure Curve* and automatic recognition and correlation of fluctuating pressure changes
- FFT module for the sequential analysis of the raw data
- Compare various sleep profiles with indication of variability
- Heart Rate Variability



- 1 Index per hour
- 3 Analysis channels
- (5) Time base analysis
- (7) Sleep stages
- 9 **Events**

2 Time Line

- **(4**) Raw data channels
- Time base raw data 6
- 8 Show sleep profile
- 10 Video screen

Different scoring modes:

for sleep staging manual

automatic

semi-manual

for events •

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- edit by key
- quick edit by mouse position •
 - edit by selection window
 - repeat mode
- * Patented